

## REMARKS

Claims 82, 85-87, 96, and 97 are present in this application. By this amendment, Claims 82 and 97 are amended and Claims 98-103 are added. The amendments and additions to the claims are supported by the specification and do not constitute new matter. Applicants respectfully request reconsideration in view of the above amendments and the following remarks.

### I. THE CLAIMS ARE PATENTABLE OVER U.S. PATENT No. 5,599,305 TO HERMANN ET AL.

Claims 82, 85-87, 96, and 97 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 5,599,305 to Hermann et al. (hereinafter "Hermann"). This rejection is respectfully traversed.

Hermann teaches an aortic introducer catheter (70) having a first inflatable balloon (76) to provide partial occlusion of blood flow and a second inflatable balloon (78) to anchor the distal end of the catheter and, in a more particular aspect, to anchor expandable grafts and other prostheses. (Col. 10, lines 29-42; FIG. 6). The device taught by Hermann has a homeostasis valve assembly (18) comprising a foam insert (38). (Col. 9, lines 58-59; FIG. 3). The foam insert (38), in its uncompressed configuration, will have an open axial lumen (52), more preferably being flared open at its proximal end (54). (Col. 10, lines 4-9; FIG. 4). As assembled, or a combination as claimed, the homeostasis valve assembly (18) comprises a compressed foam insert (38) having a reduced diameter axial lumen. (FIG. 3). Figure 3 clearly discloses that the compressed foam insert (38) has an axial lumen (52) with a reduced, yet present, diameter. Additionally, lumen connectors (80

and 82) are provided in order to connect the balloons (76 and 78) to suitable inflation sources, typically pressurized contrast medium. (Col. 10, lines 47-50).

Applicants disclose an introducer sheath device comprising a housing having a passageway that accommodates the passage of surgical components therein and sealing means for preventing the loss of blood from the vessel during the insertion and subsequent removal of surgical components during the surgical procedure. The sealing means comprises a sealing cavity filled with a biocompatible sealing material and such sealing material does not therein contain a pre-formed lumen. The sealing material forms a seal around the surgical components as the components are inserted through the sealing material and removed from the introducer sheath device during the surgical procedure. Furthermore, in one embodiment of the present invention, the introducer sheath device includes at least one filling passage way, for filling an inflatable cuff, that extends along the passageway which accommodates the passage of the surgical components.

For at least the reasons set forth above, Applicants respectfully submit that Hermann fails to disclose, teach, or suggest the subject matter of the present invention. Reconsideration and withdraw of the rejection are respectfully requested.

## **II. CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully submit that the Claims of the present invention define subject matter patentable over the references cited by the Examiner and that the application is in condition for allowance. Should the Examiner believe that anything further is desirable to place the application in

better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the below listed telephone number.

Respectfully Submitted,



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re  
Application of: Howard Tanner et al.

Serial No.: 09/108,189

Examiner: J. Thissel

Filed: July 1, 1998

Group Art Unit: 3763

For: AN INTRODUCER SHEATH FOR USE DURING A SURGICAL PROCEDURE

Attorney Docket No.: 23660-00611

Assistant Commissioner for Patents  
BOX NON-FEE AMENDMENT  
Washington, D.C. 20231



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MARKED UP VERSION OF PRELIMINARY AMENDMENT

IN THE CLAIMS:

82. (Twice Amended) An introducer sheath device for use during a surgical procedure for introducing surgical components into a vessel into a patient, said introducer sheath device comprising:

a housing having a passageway that accommodates the passage of the surgical components therein;

sealing means for preventing the loss of blood from the vessel during the insertion and subsequent removal of surgical components during the surgical procedure, wherein said sealing means comprises a sealing cavity, wherein said sealing cavity is filled with a biocompatible sealing material, wherein said sealing material does not contain a pre-formed lumen, wherein said sealing material forms a seal around the surgical components as the components are inserted through said sealing material and removed from said introducer sheath device during the surgical procedure.

97. (Amended) The introducer sheath device according to Claim 96, wherein said at least one filling passageway extends along said passageway that accommodates the passage of the surgical components.